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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,991	12/15/2003	Robert Alan Goodnow JR.	21366 US1	4512

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EXAMINER	
BOWMAN, AMY HUDSON	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,991	GOODNOW ET AL.	
	Examiner	Art Unit	
	Amy H. Bowman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *2, 4, 6-13 and 15-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 12/19/05, 5/19/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 12/19/2005 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 8/15/2005 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-36 are pending in the application. Due to the petition decision of 3/13/2006, claims 1, 3, 5, 7-14, 16, 27, 30 and 32, directed to a method of identifying compounds useful for modulating body weight comprising the use of a polynucleotide having 85% homology with SEQ ID NO: 5, will be examined as the elected group, group I.

Claims 2-13, 15-36, and the subject matter that is not drawn to the polynucleotide (SEQ ID NO: 5), are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 3, 5, 7-13, 16, 27, 30 and 32 are withdrawn because they are not drawn to a polynucleotide, but rather are drawn to the protein, which is not the elected invention.

Therefore, claims 1 and 14 will be examined to the extent that they read on the elected invention, the polynucleotide, each of which were examined in the office action mailed 8/15/2005.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for assaying for the effect of a compound on body weight *ex vivo*, does not reasonably provide enablement for human *in vivo* assays. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The invention of the above claims is drawn to a method for identifying compounds comprising contacting a test compound with a nucleic acid molecule encoding a protein having an amino acid sequence that is at least 85% identical to SEQ ID NO: 6 or a fragment thereof having at least 8 amino acids and determining whether the test compound binds to the nucleic acid sequence. The invention is further drawn to administering the test compound that binds to the nucleic acid sequence to a mammal

and measuring the effect of the test compound on the body weight of the mammal. The mammal is further specified to be a mouse.

The claims read on human *in vivo* assays to test the effect of the compound on body weight, which is not enabled. The *in vivo* assays described in the specification involve prophetic examples only and have not been reduced to practice.

The specification teaches assays utilizing tissue samples, but does not offer guidance on how to perform such an assay *in vivo* in any mammal, including a human. The specification as filed does not provide adequate guidance that would show how one skilled in the art would practice the claimed invention without undue experimentation.

To practice the claimed invention, one of skill in the art would have to *de novo* determine; the stability of the compound *in vivo*, delivery of the compound to the whole organism, specificity to the target tissue *in vivo*, dosage and toxicity *in vivo*, and entry of the molecule into the cell *in vivo* and the effective action therein. Without further guidance, one of skill in the art would have to practice a substantial amount of trial and error experimentation, an amount considered undue and not routine, to practice the instantly claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Glucksmann et al. (WO 99/37679), in view of Grassie et al. (US 2003/0152973 A1) and Gu et al. (US 2004/0197766 A1).

The invention of the above claims is drawn to a method for identifying compounds comprising contacting a test compound with a nucleic acid molecule encoding a protein having an amino acid sequence that is at least 85% identical to SEQ ID NO: 6 or a fragment thereof having at least 8 amino acids and determining whether the test compound binds to the nucleic acid sequence. The invention is further drawn to administering the test compound that binds to the nucleic acid sequence to a mammal and measuring the effect of the test compound on the body weight of the mammal. The mammal is further specified to be a mouse.

Glucksmann et al. teach the identification of a G-protein coupled receptor (GPCR) and nucleic acid molecules that encode the GPCR, referred to as the flh2882 protein and the *flh2882* gene, respectively. Glucksmann et al. teach methods of identifying compounds that bind and modulate the expression of the *flh2882* gene comprising contacting a cell with a candidate compound and determining the expression of the *flh2882* mRNA or protein (see page 32). The candidate compound is therefore identified as a modulator of *flh2882* nucleic acid expression. Glucksmann et al. specifically teach a 1728 nucleotide sequence, wherein nucleotides 1-1011 are 99.7% identical to a nucleic acid molecule encoding the instant protein (see instant SEQ ID NO: 5). The sequence of Glucksmann et al. is considered to be within the genus of polynucleotides instantly claimed, as the sequence comprises a sequence 99.7%

identical to instant nucleic acid SEQ ID NO: 5, and both are disclosed to be G-protein coupled receptor sequences. The sequence taught by Glucksmann et al. is considered to have the same function as the instant polynucleotide, as it comprises a portion that is 99.7% identical to instant SEQ ID NO: 5. Additionally, the human and mouse "mammalian sequence #115" are disclosed as being extremely similar (see instant figure 4). Therefore, the sequence taught by Glucksmann et al. is considered to be substantially similar to the mouse sequence as well. Glucksmann et al. teach expression of the sequence in recombinant mammalian cells, and further teach a mouse and human gene sequence.

Glucksmann et al. do not teach an assay to test the effect of the compound on body weight.

Grassie et al. teach a full-length cDNA sequence that codes for a GPCR, as well as the complete gene and the encoded protein. Grassie et al. teach a recombinant cell line expressing these receptors such that novel compounds active at these receptors can be identified for therapeutic use (see abstract). Grassie et al. teach that many GPCRs are expressed in the brain and may be exploited as therapeutic targets for the treatment of CNS disorders and specifically teach a GPCR, ORG3, that has a high degree of homology with human sequence flh2882 (see paragraph 19), the GPCR taught by Glucksmann et al. Grassie et al. teach that GPCRs can function to alter disease states including obesity (see paragraph 14).

Gu et al. teach assays for the identification of compounds useful for the modulation of body weight. The assays identify compounds that bind to 58128, a

GPCR. Gu et al. teach *in vivo* assays to measure the effect of the compound on body weight (see paragraph 10). Gu et al. teach that modulators of 58128 can act as therapeutic agents for treating one or more of GPCR associated disorders, e.g., disorders encompassing a CNS function involved in the regulation of body weight or body fat metabolism (see paragraph 25).

It would have been obvious to one of ordinary skill in the art to incorporate an assay to test the effect of the compound on body weight into the method taught by Glucksmann et al.

One would have been motivated to incorporate an assay to test the effect of the compound on body weight into the method taught by Glucksmann et al. because GPCRs were known in the art to be useful for modulating body weight, as taught by Grassie et al. and Gu et al.

Gu et al. specifically teaches *in vivo* assays to measure the effect of compounds that modulate GPCRs on body weight (see paragraph 10). Gu et al. teach that disorders encompassing a CNS function involved in the regulation of body weight or body fat metabolism are GPCR associated disorders (see paragraph 25). Grassie et al. teach that GPCRs can function to alter disease states including obesity (see paragraph 14). Since disorders related to body weight were known to be GPCR associated disorders, one would have been motivated to test for such an effect with the compounds identified by Glucksmann et al. to be modulators of a GPCR.

Finally, one would have a reasonable expectation of success given that *in vivo* assays were known to be beneficial to measure the effect that a compound that binds to

a GPCR has on body weight, as taught by Gu et al. One would expect for this assay to be just as beneficial in the method taught by Glucksmann et al. regarding identifying modulators of a GPCR.

Thus in the absence of evidence to the contrary, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is 571-272-0755.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Amy H. Bowman
Examiner
Art Unit 1635

JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER